



## Waiver to Allow Participation in a Food and Drug Administration Advisory Committee

DATE: October 28, 2008

TO: Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy  
Food and Drug Administration

THROUGH: Vince Tolino \_\_\_\_\_/S/\_\_\_\_\_  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

Michael F. Ortwerth, Ph.D. \_\_\_\_\_/S/\_\_\_\_\_  
Director, Advisory Committee Oversight and Management Staff  
Office of Policy, Planning, and Preparedness

FROM: Igor Cerny, Pharm.D. \_\_\_\_\_/S/\_\_\_\_\_  
Director, Advisors and Consultants Staff  
Center for Drug Evaluation and Research

Name of Advisory Committee Member: Fernando Martinez, M.D

Committee:

Joint meeting of Pulmonary-Allergy Drugs Advisory Committee, Drug Safety and Risk Management Advisory Committee, and the Pediatric Advisory Committees

Meeting date: December 10-11, 2008

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of the Financial Interest(s):

Fernando Martinez, M.D., currently serves on [REDACTED] Respiratory Advisory Board which talks about [REDACTED] and strategies for the treatment of childhood asthma. [REDACTED] is an approved competing product which can be potentially affected by the committee's discussions and recommendations.

The magnitude of the interest is between \$5,001 and \$10,000.

Description of the Particular Matter to Which the Waiver Applies:

Dr. Martinez has been asked to participate in the meeting to discuss the benefit risk assessment of long acting beta-2 adrenergic agonists for the treatment of asthma in adults and children.

Long-acting beta agonists (LABAs) are a class of medications used for the treatment of asthma. In June 2005, the safety of this class of medications was discussed at a Pulmonary Allergy Drugs Advisory Committee (PADAC) meeting. Questions posed to the committee included withdrawal of LABAs from the market. The risk benefit assessment of long-acting beta agonists is being brought to this advisory committee meeting again to address concerns raised during a Pediatric Advisory Committee meeting in November 2007. Discussion will include a focus on the safety of LABAs in pediatric patients with asthma.

Additional Facts: none

Basis for Granting the Waiver:

First, Dr. Martinez's interest is not so substantial as to preclude his participation. Dr. Martinez receives minimal compensation from [REDACTED] for serving on the advisory board.

Second, it is important to note that [REDACTED] is already approved and marketed for use in the treatment of asthma. [REDACTED] is not only indicated for the treatment of asthma but is also used for [REDACTED]. It is unclear whether any recommendations that Dr. Martinez would make, to the Food and Drug Administration regarding long acting beta-2 adrenergic agonists, would have a significant impact on [REDACTED]. It has been on the market for [REDACTED] years. In addition, [REDACTED] discovers, develops, manufactures, and markets a diverse group of products. Even if there was an impact on [REDACTED], they do not depend on one or two products for their economic success.

Third, according to the Review Division, the uniqueness of Dr. Martinez's qualification justifies granting this waiver. Dr. Martinez's expertise is in asthma and asthma-related traits in early life. His research experience includes; over 20 years of designing, conducting, analyzing, and publishing data from prospective birth cohorts enrolled either during the pregnancy stage or the first days of life stage, pharmacogenetics of asthma, and the role of gene environment interactions in the development of asthma and related traits. He was a co-investigator in the Tucson Children's Respiratory Study, a large prospective study in thousands of young children conducted over many years that essentially defined the natural history of wheezing in children in the United States. Dr. Martinez's expertise in the safety of long-acting beta-2 adrenergic agonists in the pediatric population is evident by his service as a member of the Expert Panel, National Asthma Education and Prevention Program. This body develops the treatment guidelines for asthma in the United States, including the use of long-acting beta agonists in both children and adults. His wide teaching experience includes courses in epidemiology and genetics, expertise not held by other members on the committee. Dr. Martinez's expertise is extremely relevant since the

information to be presented at the meeting is largely derived through the employment of epidemiological methods not generally used in individual clinical trials. Moreover, Dr. Martinez was a committee member for the June 2005 PADAC meeting regarding the safety of LABAs. It is important to include individuals who have participated in the ongoing risk benefit assessment of this class of medications.

Fourth, the difficulty of locating a similarly qualified individual without a disqualifying financial interest to serve on the committee also justifies granting this waiver. Because part of the focus of this meeting will be the safety of LABAs in pediatric patients with asthma, it is important to have members with this area of expertise. From the pediatric pulmonary community, two other pediatric pulmonologists were invited. One individual was recused from the meeting and the other is able to attend. However, Dr. Martinez alone has the unique expertise and knowledge of the natural history of the disease, the genetics of asthma, and early development and risk factors surrounding the pediatric asthma population. In addition, he has expert insight into the risk benefit considerations in the therapeutic management of asthma. Without Dr. Martinez's pediatric pulmonary epidemiologic expertise, the Committee will not be able to fully evaluate the risks and benefits of long acting beta agonists in children. This area of expertise is not adequately represented by other members on the Committee but is essential to provide a thoughtful and expert discussion about the issues being brought before the Committee. Consequently, the Division requests that a waiver be granted for Dr. Fernando Martinez to participate as there has been a genuine effort to secure individual participation and representation with minimal conflict of interest.

Thus we are requesting a waiver for Dr. Fernando Martinez, a temporary voting member of the Pulmonary-Allergy Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a) as well as the conflict of interest prohibitions of section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act .

Certification:

The individual may participate – The need for the Special Government Employee’s services outweighs the potential for a conflict of interest.

The individual may participate – The individual’s participation is necessary to afford the advisory committee essential expertise.

Limitations on the Regular Government Employee’s or Special Government Employee’s Ability to Act:

Non-voting

Other (specify):

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\_\_\_\_\_

Denied – The individual may not participate.

\_\_\_\_\_/S/\_\_\_\_\_  
Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy

\_\_11/17/08\_\_  
Date